

2007/0080073, the US Patent Application Publication corresponding to the present application. Hence, no new matter has been added.

Request for Reconsideration

The present invention is directed to electrochemical sensor strips and methods that increase the linearity of the correlation between the output current values recorded from the sensor strip and the substrate concentration of the sample. Different reagent compositions including soluble redox species having different redox ability, thus being substantially oxidizable or reducible (but not both) during the analysis may be deposited on two or more electrodes of a sensor strip. Additionally, the soluble redox species used at one of the electrodes may include both oxidizable and reducible species (preferably of the same redox couple) together in a ratio that provides the desired redox ability to the electrode. In this way, for example, if an electroactive organic molecule is used at the working electrode, and an inorganic coordination complex is used at the counter electrode, the desired operating potential between the electrodes may be provided by altering the ratio of the oxidizable to the reducible species of the inorganic coordination complex at the counter electrode.

As amended, claim 1 describes an electrochemical sensor strip having at least two electrodes, where the second electrode includes first and second redox species in a molar ratio greater than 1.2:1. Claim 1 addresses sensor strips where during an analysis oxidation occurs at the working electrode while reduction occurs at the counter electrode; and sensor strips where during an analysis reduction occurs at the working electrode while oxidation occurs at the counter electrode. Thus, the claim specifies that the first soluble redox species is capable of undergoing a redox reaction opposite that of the substrate.

Claim 30 is directed to the circumstance where oxidation occurs at the first electrode while reduction occurs at the second electrode during an analysis. As amended, claim 30 describes an electrochemical sensor strip where the second electrode includes first and second redox species in a molar ratio greater than 1.2:1,

but where the first redox species is reducible and the second redox species is oxidizable. Thus, for claim 30, an increased ratio of the reducible species in relation to the oxidizable species of the redox couple at the second electrode may provide an operating potential at the second electrode that is preferred for the electroactive organic molecule at the first electrode.

As amended, claim 61 describes a method of quantifying a substrate in a sample where the method provides a substantially linear correlation from zero to about 400 mg/dL between current output and substrate concentration. An electroactive organic molecule is present at a first electrode and a metal complex is present at a second electrode.

The Claims are Not Anticipated by or Obvious Over the Cited Art

The rejection of the claims as being anticipated by U.S. Pat. No. 6,287,451 ("Winarta") or obvious over *Winarta* in view of U.S. Pat. Pub. No. 2001/0006149 ("Taniike"), *Morris*, or U.S. Pat. No. 5,520,786 ("Bloczynski") is respectfully traversed.

Teachings of The Applied References

Winarta teaches a sensor strip having working and counter electrodes made from the same reagent composition, except that the counter electrode lacks an enzyme. Col. 8, Lines 37-47. The same oxidized form of a redox mediator (potassium ferricyanide) is used at both electrodes ("Reagents 1 and 2 comprise the oxidized form of a redox mediator..."). Col. 9, Lines 15-19. This formulation also is described in Col. 10, Lines 44-46 and Lines 53-56, where only potassium ferricyanide is included in the reagent compositions. Thus, *Winarta* teaches that the oxidized (thus reducible) form of the same potassium ferricyanide redox mediator is present at both the working and counter electrodes, with the difference between the electrodes being that the enzyme is present at the working, but not the counter electrode.

Taniike teaches sensor strips where the enzyme is present at the working, but not at the counter electrode, and where a ferricyanide mediator is present at the

counter, but not at the working electrode. Para. [0050]. *Taniike* also teaches the use of electroactive organic molecules as mediators and that the reagent layers of the working and counter electrodes may be made from different compositions that are separated from each other. Para. [0036] and [0030]. Furthermore, each of the examples in the patent describe sensor strips where an enzyme, but no mediator, is deposited at the working electrode, while a mediator, but no enzyme is deposited at the counter electrode. Thus, the difference between the compositions at the working and counter electrodes of *Taniike* is whether an enzyme or a mediator is present.

Morris teaches that ruthenium (III) hexamine may be used as an alternate to potassium ferricyanide as a redox mediator. Pg. 2, Para. 1. *Bloczynski* teaches the use of 3-phenylimino-3H-phenothiazine and 3-phenylimino-3H-phenoxazine as electrochemical mediators.

Anticipation

As filed, claims 6, 7, 14-17, and 33 were stated in the office action to be obvious, but not anticipated, over the cited references. Independent claims 1 and 30 were amended to include the limitations of claim 6, thus rendering the rejection of independent claims 1 and 30 and their associated dependent claims under 35 U.S.C. § 102(b) moot.

Method claim 61 was stated in the office action to be anticipated as *Winarta* teaches a first reagent layer comprising an oxidoreductase and an electroactive organic molecule (c. 10, l. 49-52). This is incorrect, as *Winarta* fails to teach the use of an electroactive organic molecule, instead teaching the combination of an enzyme with potassium ferricyanide (a transition metal coordination complex). The rejection of independent claims 1, 30, 61, and their respective dependent claims under 35 U.S.C. § 102(b) should be withdrawn because claims 1 and 6 have been amended to include subject matter previously determined not to be anticipated and because *Winarta* fails to teach the electroactive organic molecule specified in claim 61.

Obviousness

As amended, claims 1 and 30 specify that the molar ratio of the first soluble redox species to the second soluble redox species is greater than 1.2:1 prior to use of the sensor strip in an analysis. In combination, *Winarta* and *Taniike* fail to teach a sensor strip having a molar ratio of a first soluble redox species to a second redox species of greater than 1.2:1 prior to use.

The office action correctly states that paragraph 48 of *Taniike* teaches that ferricyanide is converted to ferrocyanide at the working electrode during the analysis. In fact, paragraph 48 of *Taniike* continues, stating that ferrocyanide is oxidized to ferricyanide at the working electrode and that ferricyanide is reduced to ferrocyanide at the counter electrode during the analysis. However, these statements provide no teaching or suggestion to Applicants' claims specifying a ratio greater than 1.2:1 prior to use at a second electrode (in the context of *Taniike*, Applicants' second electrode corresponds to the counter electrode).

Furthermore, nothing in *Taniike* teaches or suggests that an electroactive organic molecule should be used at a first electrode (in the context of *Taniike*, Applicants' first electrode corresponds to the working electrode), while a metal complex is used at a second electrode as specified in Applicants' claims (in the context of *Taniike*, Applicants' second electrode corresponds to the counter electrode). In contrast, *Taniike* teaches that no mediator should be used at the working electrode, a teaching in direct opposition to Applicants' claims, where a mediator in the form of an electroactive organic molecule is specified at a first electrode.

Taniike teaches that potassium ferricyanide mediator (a transition metal coordination complex in the context of Applicants' claims) only should be present at the counter electrode, while *Winarta* teaches that a mediator, such as potassium ferricyanide, should be used at both the working and counter electrodes. As the teachings of *Winarta* are in direct opposition to the teachings of *Taniike*, the combination cannot be made as it would destroy the respective purposes of the

references. *Winarta* further teaches away from present claims 1 and 30, teaching that ferricyanide should be used at both electrodes.

Even if selected portions of the combined references were improperly combined using the hindsight of Applicant's disclosure and claims, the combination fails to teach or suggest that different electron transfer molecules should be used at the working and counter electrodes or that a ratio favoring one redox species over the other of a redox pair should be used at any electrode prior to the use of the sensor strip for an analysis. Thus, even in combination, the cited references fail to provide or suggest the invention of claims 1 and 30 as amended.

Applicants' respectfully request that the rejections under 35 U.S.C. § 103(a) of independent claims 1 and 30, and their respective dependent claims, be withdrawn. The remaining rejections under 35 U.S.C. § 103(a) of claims 14-17 and 33 are believed obviated by the amendments to independent claims 1 and 30.

Method claim 61 was amended to specify a method where the correlation between the current and the concentration of the substrate is substantially linear from zero to a substrate concentration of about 400 mg/dL. This limitation is disclosed neither explicitly nor inherently by the cited references. Furthermore, none of the references, alone or in combination, teach a method of analysis where a substrate is quantified in a sample with a sensor strip having an electroactive organic molecule at a first electrode and a metal complex at a second electrode.

Conclusion

The Applicants believe the Examiner's concerns have been addressed to overcome the rejections. Upon the indication of allowable subject matter, the Examiner is respectfully requested to telephone Jonathan M. Blanchard at 312-612-6700 to resolve any outstanding issues as expeditiously as possible so the case may be passed to issue.

Respectfully Submitted,

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Date

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